



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0068]

International Conference on Harmonisation; S10 Photosafety Evaluation of Pharmaceuticals;
Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “S10 Photosafety Evaluation of Pharmaceuticals.” The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This guidance outlines details on when photosafety testing is warranted and on possible assessment strategies; it should be read in conjunction with the ICH M3(R2) guidance, section XIV(14) Photosafety Testing. The purpose of the guidance is to recommend international standards for photosafety assessment and to harmonize such assessments that support human clinical trials and marketing authorization for pharmaceuticals. This guidance finalizes the draft guidance issued on February 4, 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and

Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Regarding the guidance: Abigail Jacobs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6474, Silver Spring, MD 20993-0002;

Regarding the ICH: Michelle Limoli, Center for Drug Evaluation and Research, International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1174, Silver Spring, MD 20993-0002, 301-796-8377.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory Agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input

from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CDER and CBER, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the Federal Register of February 4, 2013 (78 FR 7786), FDA published a notice announcing the availability of a draft guidance entitled “S10 Photosafety Evaluation of Pharmaceuticals.” The notice gave interested persons an opportunity to submit comments by March 21, 2013. Changes made to the guidance took into consideration written comments received. In addition to editorial changes primarily for clarification, the major changes are as follows:

- The guidance further emphasizes the flexibility and optional nature of assessments for photosafety. This is reflected in revisions to Figure 1 and related text.
- The discussion about pharmaceuticals given via ocular routes was reduced because the ICH working group did not have useful guidance to provide for these products.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory Agencies in November 2013.

The ICH S10 guidance provides guidance on when photosafety testing is warranted, and on possible testing strategies. It represents the consensus that exists regarding assessment of photosafety to support clinical development and marketing authorization of pharmaceuticals. It supplements the ICH M3(R2) guidance,¹ which: (1) Provides certain information regarding timing of photosafety testing relative to clinical development and (2) recommends that an initial assessment of photoreactive potential be conducted and, if appropriate, an experimental evaluation be undertaken before exposure of large numbers of subjects.

The guidance describes a flexible, integrated process that involves photochemical characteristics, data from nonclinical studies, and human safety information. Although the strategy is flexible and the options selected are the developer's choice, characterization of the ultraviolet-visible absorption spectrum is recommended as the initial assessment and can obviate any further photosafety evaluation. Results of the evaluation determine the need for risk minimization measures to prevent adverse events in humans.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

¹ See the ICH guidance "M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals," available on the Internet at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>,
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,
or
<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: January 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.